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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

09/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,732	Applicant(s) KAWASHIMA, YASUYUKI	
	Examiner Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-21, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-21, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/13/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Request for continued examination (i.e., R.C.E.) under 37 C.F.R. §1.114, including the fee set forth in 37 C.F.R. §1.17(e), was filed in this application on 13 July 2009 after a Final action mailed 12 March 2009. Since this application is eligible for continued examination under 37 C.F.R. §1.114, and the fee set forth in 37 C.F.R. §1.17(e) has been timely paid, the finality of the previous Office action mailed 12 March 2009 has been withdrawn pursuant to 37 C.F.R. §1.114. Accordingly, an R.C.E. has been established and the action on R.C.E. follows.

Informal Matters

2. The remarks and amendment filed 13 July 2009 are acknowledged and entered.
3. Regarding the Informal matters pertinent to the statement in the Interview Summary mailed 12 February 2009 summarizing the discussion between the Examiner and Applicant's Representative in the Office Action mailed 12 March 2009, the Examiner would respectfully submit that Examiner stands corrected that the Representative did mention during the Interview on 09 February 2009 about filing an appeal.
4. Regarding the point of Representative mentioning in the Interview on 09 February 2009 about filing an appeal, as Applicant mentions in the remarks filed 07/13//2009 (Page 5, Line 16), said point is moot in view of the amendments filed 07/13/2009 and Applicant's admission on record that the Applicant has "opted to forego the appeal process to which" the Applicant is entitled (Remarks filed 07/13//2009, Page 5, Lines 22-23). Furthermore, the record is now clear regarding said point.

Rejection Withdrawals

5. In view of Amendments and Remarks filed 07/13//2009 accompanying response cited *supra*, following rejections in the Office Action mailed 12 March 2009 are hereby withdrawn:
- Written Description rejection to Claims 19-21 and 26 under 35 U.S.C. §112, first paragraph; and

- Indefiniteness rejection of Claims 19-21 and 26 under 35 U.S.C. §112, second paragraph.

Claims Status

6. Claims 1-10, 22-24 and 27 have been cancelled.
7. Claims 19-20 and 26 have currently been amended.
8. Claims 11-21 and 25-26 are currently pending and are examined on merits.

Information Disclosure Statement

9. The Information Disclosure Statement (i.e., IDS) filed 13 July 2009 has been made of record, considered and duly initialed copies of appropriate USPTO form are enclosed with the instant Office Action.

Claim Rejections – 35 U.S.C. § 102

10. The following is a new rejection in view of newly performed search and Applicant's newly filed IDS on 07/13/2009.
11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 11-17 and 25 are rejected under 35 U.S.C. §102(b) as anticipated by Wallner et al (1997. Flow Sorting of Microorganisms for Molecular Analysis Applied and Environmental Microbiology, Volume 63, Pages 4223–4231).

Claims 11-17 and 25 recite an apparatus to measure bacteria, said apparatus comprising a sampling device, a first detector, a second detector, and a control unit.

Regarding Claims 11-17 and 25, Wallner et al., teach a flow cytometer equipped with a sampling component, detectors for forward-angle light scatter and right-angle light scatter. Additionally, said unit scatters the fluorescence after excitation with the second laser tuned to ultra violet. The Normal-R” modus in said device gives both high purity and recovery. The device is also equipped to define sort criteria and additionally in what format to obtain the scatter of the data for the scattergram. With said device, data are collected in list mode as pulse height signals (four decades in logarithmic scale each). In said device, sort criteria are defined by drawing polygonal gates in bivariate histograms (dot plots of the two most informative flow cytometric parameters). Furthermore, inclusion of included population for measurement is checked through directly sorting onto microscopic slides (Page 4224, Column 1, Lines 40-63). Please note further that despite the fact that the functional intended use of a device does not carry any patentable weight, Wallner et al., also teach bacterial counting, size distribution, scattergram in a straight line and further a distinction between bacilli and cocci type bacterial morphologies (Figures 1-2, 4 and Table 2). The functional intended use of a device does not carry any patentable weight because a device is construed as a machine having different components and, in this case, the functional intended use of the machine does not physically alter the machine *per se*. Thus, Wallner et al., teach a bacterial measuring apparatus comprising a sampling device, two different detectors, a control unit that creates a scattergram, analyzes cell size distribution and the bacterial morphology within said sample, representing a distribution state, maximum variance direction of the distribution, a slope of the maximum distribution, detector detecting light scattered from the light from the bacteria. Even though Wallner et al., are silent regarding explicit description of detector comprising a member having a pore for passing through the bacteria and a flow-cell for flowing the sample; instantly claimed claims 11-17 and 25 are anticipated by the Examiner-cited prior art reference because Wallner et al's apparatus/device would inherently comprise said components. Therefore, the prior art device must function as claimed because the said prior art apparatus/device is comprised of same components and is being applied for the same intended functional use as the claimed apparatus (See e.g., *In re Best*, 195 USPQ 430, 433-CCPA 1977).

Therefore, the reference is deemed to anticipate the cited claims.

13. Claims 11-15, 17, 19, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda et al (US Patent 6,165,740).

Claims 11-15, 17, 19, and 25 recite an apparatus to measure bacteria, wherein said apparatus comprises a sampling device, a first detector, a second detector, and a control unit.

Fukuda et al., teach a flow cytometry device, wherein the sample stream is irradiated with light, and scattered light and fluorescent light emitted from the particles is detected (see, for example, col. 6, lines 1-15). When analyzed by said flow cytometry device, the aggregates of particles, i.e., bacteria reflect fluorescent light and scatter other light differently, allowing a sensor to discern between the two types of bacteria (Abstract; Column 3 line 61 to Column 4 line 48; Column 6 line 25 to Column 8 line 10, as examples). Additionally, said unit is equipped with an analysis capability which can diagram particle distributions in two dimensions, from which any required information such as slope of distribution can be measured, reading on instant claims 12-14 (e.g., Figure 29). Said device distinguishes between *Staphylococcus* and *Bacillus* bacteria in a sample by analyzing the sample.

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 U.S.C. §103

14. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 11-21 and 25-26 are newly rejected under 35 U.S.C. § 103(a) as obvious over combined teachings from Wallner et al (1997. Flow Sorting of Microorganisms for Molecular Analysis Applied and Environmental Microbiology, Volume 63, 223–4231) and Fukuda et al (US Patent 6,165,740, issued 26 Dec 2000) in view of Kubitschek et al (1986. Determination of Bacterial Cell Volume with the Coulter Counter. Journal of Bacteriology Volume 168, Pages 1466-1467) and further in view of Chupp et al (US Patent 5,631, I 65).

Claims 11-21 and 25-26 recite an apparatus to measure bacteria, said apparatus comprising a sampling device, a first detector, a second detector, and a control unit. Said apparatus further comprises a display unit.

Teachings from Wallner et al., and Fukuda et al., respectively have been discussed at items 12-13 *supra*.

Wallner et al., are silent regarding the first detector determining size information by detecting electrical resistance and further a display unit for determining reliability of data, or that outputs a warning when the control unit has determined that identifying bacteria type is difficult.

Kubitschek et al., teach a Coulter-type impedance detector can reliably detect bacterial cell volume. Said devices measure the size determined by impedance counter versus the size determined by pelleting cells and measuring the pellet volume versus cell count. Kubitschek et al., further teach the relationship between actual cell size and cell size determined by Coulter impedance counter is reliably the same (See, e.g., Page 1466, Column 1, ¶ and Figure 1). Kubitschek et al. conclude "the agreement between mean cell volumes measured by the two methods provides evidence that cell volumes determined with the Coulter Counter-Analyzer system are in substantial agreement with the values determined biophysically for the same cells, thereby validating the use of electronic cell sizing for measurements of bacterial volumes" (Page 1467, Column 2, final paragraph).

Chupp et al., teach a single instrument can comprise both an impedance transducer and an optical flow cell transducer for detecting light scattering and fluorescence (see "System Overview", Column 11, lines 35-48). Chupp et al., further teach that a system can automatically determine statistical significance of the data it is collecting, and alter its actions based on its determination of statistical significance. For example, when cell counts are low, the apparatus can correct its counting time to improve statistical significance of the data rather than alter counting times; involve both apparatus determination of statistical significance and determining a response to the determined significance (Column 56, lines 25-27).

A person of ordinary skill in the art at the time the invention was made would have been motivated to arrange an apparatus comprising an optical cytometer and a Coulter impedance counter according to the combined teachings from Wallner et al., Fukuda et al., Kubitschek et al., and Chupp et al.; because Fukuda et al. teach a flow cytometer that scatters light in different planes distinguishing cocci and bacilli type bacterial morphologies, said apparatus determines volume of the aggregates, Kubitschek et al., teach that a Coulter counter can reliably determine bacterial cell volume, and Chupp et al., teach that one can combine a Coulter counter and an optical cytometer in a single apparatus.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to arrange a single apparatus for determining bacterial morphological species by combining an impedance analyzer with an optical flow cytometer as is taught by the combining teachings from Wallner et al., Fukuda et al., Kubitschek et al., and Chupp et al., discussed *supra*; because Fukuda et al. teach a flow cytometer that scatters light in different planes distinguishing cocci and bacilli type bacterial morphologies, said apparatus determines volume of the aggregates, Kubitschek et al., teach that a Coulter counter can reliably determine bacterial cell volume, and Chupp et al., teach that one can combine a Coulter counter and an optical cytometer in a single apparatus.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

16. No Claims are allowed for the aforementioned reasons.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kailash C Srivastava/
Examiner, Art Unit 1657

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19 September 2009

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